[0271] Study Phase Ib: Enrollment (First Site Visit)
[0272] Each qualified subject will complete and sign the informed consent form
[0273] Each subject will be assigned a subject study number
[0274] Study Phase Ic: Sample Collection (First Site Visit)
[0275] For each subject, the PI will collect the saliva DNA sample using the CoADTS Test Sample Collection Kit. The sample collection will be performed in accordance with IFU for the collection kit.
[0276] The sample collection kit will be sent to the hospital laboratory.
[0277] All information will be recorded in the appropriate CRFs.
[0278] Study Phase Id: Hospital Laboratory (First Site Visit)
[0279] The hospital laboratory will extract the DNA from the sample collection kit utilizing the DNA extraction kit provided with the CoADTS Test kit.
[0280] The laboratory will ship the extracted DNA to the CLIA laboratory
[0281] Study Phase II: Primary Outcome (Days: 0, 7, 14, 21, 28):
[0282] 1. For each subject, the PI or PI assistant will record the subject's severity of disease
[0283] 2. All information will be recorded in the appropriate CRFs

Inclusion Criteria

[0284] Male over the age of 18
[0285] First time present at the site
[0286] Laboratory confirmed SARS-CoV-2 infection
[0287] Able to give informed consent

Exclusion Criteria

[0288] Unable to give informed consent
[0289] Diagnosed with an additional respiratory co-infection
[0290] XXY males

Assessment of Efficacy

[0291] Efficacy Parameters
[0292] Severity of Disease
[0293] Clinical assessment of disease severity will be made by attending physician and reported to the PI or PI assistant. Disease severity will be categorized as: discharged, hospitalization, admission to intensive care unit [ICU] or and death.
[0294] Method and Timing
[0295] All assessments described in section 5.1 will be recorded on paper forms
[0296] (CRFs) and stored with each subject's clinical study record.
[0297] The timing to complete the assessment of efficacy will be at Baseline, Day 7, Day 14, Day 21 and Day 28. After baseline assessment, the additional assessment can be performed by computerized hospital record search by the PI or PI assistant.

Example 13

[0298] A controlled study was conducted on 100 male patients with average age of 48.3 years old. Patients were diagnosed with SARS-CoV-2 infection but were showing relatively mild symptoms. Patients were divided into one of two arms. The treatment arm was prescribed bicalutamide (50 mg) once daily at the start of the trial, the control arm received standard care. Patients were instructed to go home but return to the hospital if symptoms became worse. Efficacy parameters were defined as 1.) COVID-19 Diagnosis: COVID-19 positive diagnosis were defined as subject exhibiting symptoms of acute respiratory infection, defined as one or more of the following cough, fever (>37.5° C./99.5° F.), shortness of breath, sore throat, and a positive SARS-CoV-2 rtPCR test 2.) COVID-19 Hospitalization was defined as confirmed hospitalization due to COVID-19, and 3.) Symptoms Severity of COVID-19 was defined as symptoms severity of COVID-19 using Brescia-COVID Respiratory Severity Scale (BCRSS).
[0299] All subjects were tested and found to be positive for SARS-CoV-2 infection. All subjects were monitored for one month after the initiation of the therapy. 6 of 50 subjects in the bicalutamide arm were admitted to the hospital after their first visit. The average BCRSS score for the 6 admitted patients was 1.9. 17 of 50 subjects in the standard care group were admitted to the hospital with an average BCRSS score of 4.1.

Example 14

[0300] A controlled study was conducted on 40 male patients with average age of 41.6 years old. Patients were diagnosed with SARS-CoV-2 infection but were showing relatively mild symptoms. Patients were divided into one of two arms. The treatment arm was prescribed darolutamide (300 mg) orally twice daily at the start of the trial, the control arm received standard care. Patients were instructed to go home but return to the hospital if symptoms became worse. Efficacy parameters were defined as 1.) COVID-19 Diagnosis: COVID-19 positive diagnosis was defined as subject exhibiting symptoms of acute respiratory infection, defined as one or more of the following cough, fever (>37.5° C./99.5° F.), shortness of breath, sore throat, and a positive SARS-CoV-2 rtPCR test 2.) COVID-19 Hospitalization was defined as confirmed hospitalization due to COVID-19, and 3.) Symptoms Severity of COVID-19 was defined as symptoms severity of COVID-19 using Brescia-COVID Respiratory Severity Scale (BCRSS).
[0301] All subjects were tested and found to be positive for SARS-CoV-2 infection. All subjects were monitored for one month after the initiation of the therapy. 1 of 20 subjects in the darolutamide arm was admitted to the hospital after their first visit. The patient's BCRSS score was 2. 3 of 20 subjects in the standard care group were admitted to the hospital with an average BCRSS score of 3.6.

Example 15

[0302] A controlled study was conducted on 150 male patients with average age of 45.7 years old. Patients were diagnosed with SARS-CoV-2 infection but were showing relatively mild symptoms. Patients were divided into one of two arms. The treatment arm was prescribed abiraterone (500 mg) twice daily at the start of the trial, the control arm received standard care. Patients were instructed to go home but return to the hospital if symptoms became worse. Efficacy parameters were defined as 1.) COVID-19 Diagnosis: COVID-19 positive diagnosis was defined as subject exhibiting symptoms of acute respiratory infection, defined